



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

gsl
Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

February 10, 2005

Ref: 2005-DAL-WL-13

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Brain Watts, President
Spectrum Laboratories, Inc.
18617 Broadwick Street
Rancho Dominguez, California 90220-6425

Dear Mr. Watts:

On November 17 through December 6, 2004, the United States Food and Drug Administration (FDA) conducted an inspection of Hydro-Med Products, Inc. (Hydro-Med), a Division of Spectrum Laboratories, Inc., located at 2930 Ladybird Lane, Dallas, Texas 75220. Hydro-Med manufactures sterile stockinettes (surgical drapes), sterile Esmarch bandages, and sterile equipment drapes for ultrasound, arthroscopic, camera, and endoscopic accessories. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The FDA inspection revealed that your devices are adulterated and misbranded within the meaning of the Act. Your devices are adulterated within the meaning of Section 501(h) of the Act because the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Your devices are misbranded within the meaning of Section 502(t)(2) of the Act because your firm failed to submit a report of correction and removal to FDA of recalled medical devices, as required by Section 519(f)(1) of the Act and Title 21, Code of Federal Regulations (CFR), Part 806.

Quality System Regulation

At the close of the inspection, your firm was issued a List of Inspectional Observations, Form FDA-483 (copy enclosed), which identified a number of significant QS Regulation violations including, but not limited to, the following:

1. Failure of the management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization, and failure to allocate necessary resources, including the assignment of trained personnel for management, performance of work, and assessment activities, as required by 21 CFR 820.20 [FDA-483, Items 1 through 10]. For example, you failed to provide sufficient personnel to assure that all procedures are appropriately carried out as required by the quality system. Your quality manager, who is the management representative that monitors and reports the performance of your firm's quality system, is a part time employee.
2. Failure to adequately investigate the cause of nonconformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2) [FDA-483, Item 1]. For example, in September 2000, your firm recalled 350 sterile ultrasound probe drapes due to defective pouch seals. These 350 probe drapes were part of a total shipment of [REDACTED] pouches. However, you failed to investigate and document potential packaging defects for the remaining [REDACTED] pouches.
3. Failure to adequately validate manufacturing processes with a high degree assurance and approve them according to established procedures to ensure that product specifications can be consistently met, as required by 21 CFR 820.75(a) [FDA 483, Item 2]. Your firm's validation of the heat seal process for sealing device packaging is inadequate. For example:
 - a) Your firm has not defined process limits for worst case conditions for pouch size and material, product size, conveyor speed of feeding pouches, the orientation for feeding pouches, and thermocouple temperature ranges; and
 - b) Your firm has not established a valid statistical rationale to demonstrate why a sample size of [REDACTED] pouches [REDACTED] with [REDACTED] [REDACTED] with [REDACTED] product, and [REDACTED] is sufficient to detect product variability; and
 - c) Your firm has not determined and documented the effect of a single run on multiple runs of the [REDACTED] sterilization on the pouch material and seal integrity. Additionally, your firm has not performed inspections or mechanical seal testing to verify the seal integrity after sterilization; and

- d) Your firm has not documented any types and sizes of the pouches used during the heat seal validation and revalidation process; and
 - e) Your firm has not defined the circumstances under which a revalidation of the heat seal process is required.
4. Failure to establish and maintain procedures for monitoring and control of process parameters and component and device characteristics during production to ensure a device conforms to its specifications, as required by 21 CFR 820.70(a)(2), and failure to monitor and control process parameters for validated processes to ensure that the specified requirements continue to be met, as required by 21 CFR 820.75(b) [FDA-483, Items 2, 5]. For example, your firm has not monitored the heat seal temperatures during production to assure they are set within the specified temperatures established during the validation of heat seal process. Our investigator observed that one of the [REDACTED] temperature gauges was set outside the specified temperature range on at least three occasions. Your heat seal validation conducted on 3/9/01 suggested that a sealing temperature at and above [REDACTED] F may compromise the seal integrity (e.g., the paper side of the pouch tore when pulled or the [REDACTED] side of the pouch torn). However, on 12/2/04 and 11/22/04 the temperature gauge was set at [REDACTED] F, which is 5° F above the upper limit of [REDACTED] F. On 11/24/04 it was set at [REDACTED] F, which is 19° F above the upper limit.
5. Failure to establish and maintain acceptance procedures to ensure that specified requirements for in-process product are met, as required by 21 CFR 820.80 (c) [FDA-483, Item 2(6), 2(9), and Item 5(2)]. For example, your firm has not quantitatively defined acceptance specifications and test methods for the acceptance or rejection of seal strength. Instead, your current testing is based on subjective evaluation by the packaging supervisor during production. You have not shown that you have adequately assured that the subjective evaluation [REDACTED] observation or [REDACTED] test) equals the seal strength specification of [REDACTED] per inch.
6. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a) [FDA-483, Item 6]. Your firm has not consistently conducted [REDACTED] seal strength tests (mechanical testing) and evaluation as per your firm's procedures. For example:
- a) Mechanical seal strength testing was not always conducted on the first week of the [REDACTED] fiscal [REDACTED] as set by your firm; and

- b) Mechanical seal strength testing conducted on 6/14/04 of lot B5065 contained discrepancy between the test results recorded on the seal strength test data sheet and the raw data recorded on the strip chart; and
 - c) Your firm failed to follow its sampling procedure in that you have not documented at which point in the production process the pouches were pulled for seal strength testing (i.e. [REDACTED] or [REDACTED] of a production work order); and
 - d) Your firm failed to follow its sampling plan in that the actual number of pouches pulled for seal strength testing was less than the total number of pouches required by your procedures.
7. Failure to establish and maintain procedures for implementing corrective and preventive action and to include documentation of the verification or validation of corrective and preventive action activities, as required by 21 CFR 820.100(a) and (b) [FDA-483, Item 9]. For example, your firm has received a number of recurring complaints of hair and other contaminants in the sterile device packages. Your corrective and preventive action activities concerning these complaints were neither documented nor verified to ensure such actions are effective.
8. Failure to establish and maintain procedures to adequately control environmental conditions to prevent their adverse effects on product quality, as required by 21 CFR 820.70(c) and to prevent contamination of equipment, or product as required by 21 CFR 820.70(e) [FDA-483, Item 7]. For example, your firm failed to conduct environmental testing on a [REDACTED] schedule as required by your firm's environmental testing procedures.

Correction and Removal Regulations

Your devices are also misbranded within the meaning of Section 502(t)(2) of the Act because a report of correction or removal was not submitted to FDA as required by Section 519(f)(1) of the Act. The Correction and Removal Regulations in 21 CFR Part 806, promulgated under Section 519(f)(1), require manufactures and importers to report to FDA, within 10 working days, any correction or removal of a device to reduce a risk to health. See 21 C.F.R. § 806.10(e)(1).

On or about September 28, 2000, your firm recalled 350 sterile ultrasound probe drapes from the market due to defective packaging that led to a potential breach in sterility. Your firm's action to retrieve these products meets the definition of a "removal," as defined in 21 CFR § 806.2(i). Therefore, under 21 CFR § 806.10(a)(1), you had 10

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working days to report your removal of these devices from the market. However, you failed to report the recall activities to FDA.

Spectrum Laboratories' Response

We acknowledge receiving your firm's letter, dated January 5, 2005, responding to the Form FDA-483 issued to your firm at the conclusion of our last inspection. Your firm promised to correct FDA's observations and outlined a general corrective action plan with time frames for completion ranging from January through October 2005. However, your firm's response is incomplete unless and until you provide update reports that document specific corrective action activities your firm has taken and verified the effectiveness of the corrective actions to address the specific FDA-483 observations and issues identified in this letter.

Due to the serious nature of the observations and the lack of executive management controls at Hydro-Med, we suggest you obtain the assistance of independent third-party regulatory/technical consultants. These consultants can help your firm identify and correct all systemic problems and train your staff to sustain a state of compliance with the CGMP requirements of the QS Regulation.

Responding to This Letter

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter and in the Form FDA-483 may be symptomatic of other serious underlying problems in your firm's manufacturing and quality assurance systems. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

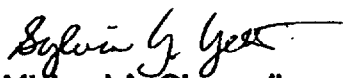
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken, or will take to identify and correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to ensure that similar violations will not recur.

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Your reply should be directed to Thao Ta, Compliance Officer, at the address indicated on the above letterhead.

Sincerely,


for Michael A. Chappell
Dallas District Director

MAC:txt

cc:

Mrs. Bonnie J. Beasley, Plant Manager
Hydro-Med Products, Inc.
A Division of Spectrum Laboratories, Inc.
2930 Ladybird Lane
Dallas, Texas 75220